An issue of new matter is not raised by the amendments to the claims and specification or the addition of the new claims. A typographical error was corrected on page 6, line 12 and the notes to the colored figures have been replaced with notations to the formal figures that are black and white photographs. With respect to the claim amendments and the addition of the new claims, support is found in the specification on page 3, lines 22-30; page 4, lines 1-6; page 6, lines 1-10; page 7, lines 1-10; page 9, lines 4-15; page 9, lines 11-13; page 16, lines 17-27; page 14, lines 19-23 and line 29 to page 15, line 8; page 16, line 25 to page 17, line 8; page 15, lines 8-16; page 17, lines 30-31; page 45, lines 20-30; Figure 2 and Figure 8B. Entry of the amendments to the specification, claims and the newly added claims is respectfully requested.

In view of the preceding amendments and remarks, reconsideration and withdrawal of the rejections is respectfully requested.

Objections To Drawings

The drawings are considered to be informal because they fail to comply with 37 CFR 1.84(a)(1) which requires black and white drawings using India ink or its equivalent.

In response to this objection, new drawings are submitted herewith. The specification also has been amended to conform and describe the new drawings. In view of these amendments and submission of new figures, removal of the objection is respectfully requested.

Informalities

The disclosure is objected to because of the following informalities: on page 6, line 12, "induces" is misspelled. Claim 23 is objected to because it depends from non-elected base claim 20. Appropriate correction is required.

By this amendment and response, the misspelling on page 6 and the error in claim 23 have been corrected. Withdrawal of these objections is respectfully requested.

35 U.S.C. § 112, First Paragraph

The rejection of claims 1-6, 21, 23 and 24 under 35 U.S.C. § 112, first paragraph because the specification, while being enabling for FADD proteins identified by SEQ ID NO:2, allegedly

does not reasonably provide enablement for a FADD protein. The rejection of record was applied to claims 29 and 30 and to newly added claims 31 to 36. The Office agreed that the specification defines FADD proteins in both structural and functional terms on page 13, lines 22 to 25, but deemed that this was insufficient to enable the full scope of the claims.

Claims 3 to 5 also remain rejected under 35 U.S.C. § 112, first paragraph, allegedly because the specification, while being enabling for AU1-N-FADD and FADDmt, does not reasonably provide enablement for fragments of FADD. The rejection of record was applied to newly added claims 32 and 35. These claims are drawn to polypeptide fragments of FADD or to polypeptide fragments of FADD consisting of at least either the C-terminal or N-terminal portions of FADD. The Office noted Applicants argued that page 15, line 7 to page 16, line 16, of the specification teaches how several different fragments of FADD can be used and that page 16, line 28 through page 17, line 29, of the specification describes how FADD fragments can be made. The Office also noted that Applicants argued that the specification on page 50, lines 9-14 and on page 53, lines 1 to 18 the specification demonstrates how to make N- and C-terminal FADD fragments and how they function. However, the Office determined that because the claimed FADD encompasses any protein structure, as discussed *supra,* the fragments are not enabled.

Claims 29 and 30 remain rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for a method of screening for an agent that modulates the binding of FADD of SEQ ID NO:2 to the intracellular domain of the Fas receptor, it allegedly does not reasonably provide enablement for a method of screening for an agent useful to modulate a cellular function regulated by the Fas receptor pathway. The Office maintained that the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Applicants respectfully traverse. Without conceding the correctness of the Examiner's position, the claims have been amended to recite some structural portion of the protein shown in SEQ ID NO:2 and analogs thereof. In view of these amendments, reconsideration and withdrawal of this rejection is respectfully submitted.

35 U.S.C. § 112, Second Paragraph

Claims 21, 23 and 31 to 36 stand rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

Claims 21 and 23 were rejected on the ground that the term "the protein or polypeptide" alleged does not clearly convey if the FADD protein or polypeptide is the same as that recited in the preamble or some other protein or polypeptide.

The phrase "non-naturally occurring" allegedly renders claims 31 to 36 indefinite on the ground that the claims include proteins not actually disclosed (those encompassed by "non-naturally occurring"), thereby rendering the scope of the claim unascertainable. Further, the claims do not provide a standard by which it could be determined whether a protein is naturally or non-naturally occurring.

Applicants respectfully traverse. In view of the above amendments to the claims, the rejection of claims 21 and 23 are obviated.

With respect to the rejection of claims 31 to 36, it is well known to one skilled in the art that a "non-naturally occurring" protein or polypeptide is one that has not been purified or is not "wild-type". Examples of non-naturally occurring proteins and polypeptides include recombinantly produced proteins, analogs, variants and fusion proteins. Furthermore, Applicants respectfully request the Office to clarify the requirement that the claim itself provide a standard by which it could be determined whether a protein or polypeptide is naturally or non-naturally occurring.

In view of the preceding amendments and remarks, reconsideration and removal of the rejections is respectfully requested.

35 U.S.C. § 102

Claims 1 to 5 and 31 to 35 stand rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Itoh (T, cited in previous Office Action).

The Office argued that Itoh et al. (T) describes an isolated human Fas antigen (Figure 3, panel (b)) and a polypeptide fragment of the Fas antigen ((Figure 3, panel (c)), wherein the

polypeptide fragment consists of at least the C-terminal portion of the protein (Figure 2, F58), and wherein the polypeptide consist of at least the N-terminal protein of the protein, (Figure 2, F58 and FD5) and characterized by the ability to induce apoptosis (page 10935, Figure 4, and column 1, second sentence). The Office alleged that thus, the Fas receptor has the ability to bind the cytoplasmic regions of the Fas receptor and induce apoptosis, and the Fas receptor disclosed by Itoh et al. (T) meets all the structural and functional limitations of the claimed FADD protein.

Claims 6, 23 and 24 stand rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Itoh et al. (Ul). The Office remarked that these claims are drawn to a FADD protein or polypeptide, which has been recombinantly produced and isolated from a host cell and that the subject specification defines a FADD protein or polypeptide as having the ability to modulate cellular function associated with Fas receptor pathway (page 13, lines 22-25). The Office alleged that Itoh et al. (U1) disclose a Fas receptor which has been recombinantly produced and isolated from a host cell (Figure 3, page 236). The Office further noted that: "[a]lthough claims 23 and 24 are drawn to a product produced by a process, product-by-process claims are not limited to the manipulations of the recited steps, only the structure implied by the steps. The determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process."

Applicants respectfully traverse. Neither of the cited Itoh et al. references discloses Applicants' protein nor polypeptide. The specification clearly discloses that the claimed FADD protein or polypeptide is not the intracellular domain of the Fas receptor nor an extracellular ligand of the Fas receptor.

Nevertheless, the claims have been amended herein to recite some or all of the amino acid structure recited in SEQ ID NO:2, to overcome rejections under 35 U.S.C. § 112, first paragraph. The newly amended claims clearly distinguish the FADD and fragments thereof from the proteins and polypeptides disclosed by the Itoh et al. references.

Removal of the rejections is respectfully requested.

35 U.S.C. § 103

Claims 21 and 36 stand rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Itoh et al. (Ul) in view of Berg et al. (A). The Office remarked that the claims are drawn to a method of chemically synthesizing a FADD protein or polypeptide, and Itoh et al. (U1) provides the amino acid sequence of the Fas receptor (page 235, Figure 2). It was admitted that Itoh et al. (U1) does not disclose a process for chemically synthesizing said Fas receptor.

Berg et al. is cited for disclosing a method for the solid phase chemical synthesis of proteins in high yield and purity (column 15, line 50 to column 23, line 32), but that Berg et al. do not teach the chemical synthesis of a Fas protein.

The Office alleged that it would have been obvious to one of ordinary skill in the art to chemically synthesize a FAS protein or polypeptide, as taught by Itoh et al., using the technique taught by Berg et al., with a reasonable expectation of success. One of ordinary skill in the art would be motivated to chemically synthesize a Fas protein or polypeptide in order to produce a pure form of the protein or polypeptide with a minimum of purification steps.

Applicants respectfully traverse and incorporate by reference their remarks noted above with respect to Itoh et al. (U1). Claim 36 has been canceled herein. In view of the preceding amendments, Itoh et al. (U1) does not disclose FADD, analogs or fragments. Thus, there is no suggestion or enablement for the invention of amended claims 21. The rejection is improper and therefore should be withdrawn.

III. CONCLUSION

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, Applicants petition for any required relief including extensions of time and authorizes the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952 (Our Ref.: 20344-21070.20)**. However, the Assistant Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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Respectfully submitted,

By: _____

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